

Application No. 09/593,591

Reply dated December 9, 2008

Reply to Final Office Action of October 9, 2008

REMARKS

In the Office Action, the Examiner objected to claims 155-157 due to informalities. Applicant updated the claim status identifiers in order to overcome the objection.

The Examiner rejected claims 1, 2, 4, 5, 7-12, 14, 16, 85, 86, 88, 89, 91-96, 98, 100, 102-105, 116, 117, 163, 164, 166, 168-173, 175, 179, 180, 203, 204, 206, 208, 209, 211, 213, 215, 223, 224, 228, 229, 231, 233, 235, 239, 240, 263, 264, 266, 268, 269, 271, 273, 275, 279, and 280 under 35 U.S.C. § 102(e), as being anticipated by International Publication No. WO 98/17209 to Pafford et al. ("Pafford") or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Pafford in view of U.S. Patent No. 5,861,041 to Tienboon et al. ("Tienboon") or International Publication No. WO 99/08627 to Gresser et al. ("Gresser") or U.S. Patent No. 5,607,424 to Tropiano ("Tropiano"); rejected claims 1, 2, 4, 5, 7-20, 22, 25, 30, 32-35, 85, 86, 88, 89, 91-106, 109, 114-119, 127-129, 148, 158, 163, 164, 171, 174, 175, 179, 180, 203, 204, 206, 208-211, 213-215, 219, 220, 223, 224, 226, 228-231, 233-235, 239, 240, 263, 264, 266, 268-271, 273-275, 279, 280, 285, 288, 291, 294, 297, and 300 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,277,149 to Boyle et al. ("Boyle") in view of Tienboon or Gresser or Tropiano; rejected claims 26-29, 110-113, 149-152, 159-162, 172, 177, 178, 182, 212, 217, 218, 222, 232, 237, 238, 242, 272, 277, 278, and 282 under 35 U.S.C. § 103(a) as being unpatentable over Boyle, Tienboon, Gresser, and Tropiano, further in view of U.S. Patent No. 5,397,364 to Kozak et al. ("Kozak"); rejected claims 36-42, 120-126, 166, 168-170, 173, 181, 206, 221, 241, and 281 under 35 U.S.C. § 103(a) as being unpatentable over Boyle, Tienboon, Gresser, and Tropiano; rejected claims 23, 24, 107, 108, 176, 216, 236, and 276 under 35 U.S.C. § 103(a) as being unpatentable over Boyle, Tienboon, Gresser, and Tropiano, further in view of U.S. Patent No. 5,669,909 to Zdeblick et al. ("Zdeblick"); and rejected claims 283, 284, 286, 287, 289, 290, 292, 293, 295, 296, 298, and 299 under 35 U.S.C. § 103(a) as being unpatentable over Boyle in view of Tienboon.

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As set forth in detail below, Applicant respectfully traverses the foregoing rejections at least for the reason that the combination of references proposed by the Examiner does not disclose or suggest each and every recitation of independent claims 1, 85, 163, 203, 223, and 263.

35 U.S.C. §102(e) Rejection

Independent claims 1, 85, 163, 203, 223, and 263 recite an interbody spinal fusion implant having a body and an opening coincident with the medullary canal, "a majority of said opening as measured on the mid-longitudinal axis of said body being between said leading end of said body and a plane perpendicular to and bisecting the length of said body into two parts of equal maximum length along the mid-longitudinal axis, the plane passing through at least a portion of said opening." None of the references cited by the Examiner, whether alone or when properly combined, disclose or suggest such structure.

Pafford teaches a spinal spacer (110) having an opening (130) between a leading end (115) and a trailing end (111) of the spacer. (See Pafford, FIG. 29). As admitted by the Examiner, the "farthest point of chamber (130) extends 19 mm on either side of the bisecting plane." (Office Action, page 3, line 16). FIG. 29 of Pafford shows that the points of chamber (130) referenced by the Examiner are on the mid-longitudinal axis of spacer (110). Thus, as measured on the mid-longitudinal axis of spacer (110), the dimension of opening (130) between the perpendicular bisecting plane and leading end (115) is equal to the dimension of opening (130) between the perpendicular bisecting plane and the trailing end (111). The Examiner contends that "the area of the chamber on the leading edge is inherently greater than the portion on the trailing side." (Office Action, page 3, lines 18-19 (emphasis added).) Applicant submits that independent claims 1, 85, 163, 203, 223, and 263 do not recite an "area" of the opening. Instead, a dimension of the opening as measured on a specific line (i.e., the mid-longitudinal axis) of the implant is recited.

The Examiner asserts that in FIG. 29 of Pafford, "the trailing end is the anterior wall (111)." (Office Action, page 3, lines 11-12.) The Examiner further asserts that "the

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opening on the leading ends [sic] is inherently smaller because it is not squared off as in the trailing end." (Office Action, page 8, lines 7-8.) Applicant respectfully submits that contrary to the Examiner's assertion, FIG. 29 of Pafford shows that the trailing end (111) of the implant is not "squared off". Pafford does not disclose an implant with "a majority of said opening as measured on the mid-longitudinal axis of said body being between said leading end of said body and a plane perpendicular to and bisecting the length of said body" as recited in independent claims 1, 85, 163, 203, 223, and 263. As such, the Examiner's rejection of claims under 35 U.S.C. § 102(e) over Pafford is improper and should be withdrawn.

35 U.S.C. 103(a) § Rejections

At least for the reasons set forth in the Amendment of July 2, 2008, incorporated by reference herein, and further as set forth below, Applicant submits that the Examiner's asserted combinations of (1) Pafford with Tienboon, Gresser, or Tropiano; and (2) Boyle with Tienboon, Gresser, or Tropiano do not teach or suggest each and every recitation of Independent claims 1, 85, 163, 203, 223, and 263. Moreover, Applicant submits that the Examiner has not shown why a person of ordinary skill in the art would have had a reason to modify Pafford or Boyle in view of Tienboon, Gresser, or Tropiano to result in Applicant's claimed invention.

Boyle teaches an implant having an opening (26) between the leading and the trailing ends of the implant. (See Boyle, FIGS. 10-12, 19). The Examiner admits that "Boyle does not disclose that the opening can have a majority of it between the leading end and the plane bisecting the length into two equal parts as claimed." (Office Action, page 5, lines 5-7). The Examiner combines each of Pafford and Boyle with Tienboon, Gresser, or Tropiano, and contends that Tienboon, Gresser, and Tropiano "each suggest that it was known to make openings in spinal implants that are off center and closer to a leading edge than to a trailing edge." (Office Action, page 4, lines 1-3, page 5, lines 8-9).

Applicant submits that each of Tienboon, Gresser, and Tropiano teaches away from Pafford and Boyle and from Applicant's claimed invention. As identified by the

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Examiner, Pafford and Boyle each discloses a bone ring obtained from a long bone. Conversely, none of Tienboon, Gresser, and Tropiano teach or suggest a spinal implant obtained from a major long bone of a human and having a body manufactured from a bone ring having a medullary canal. Tienboon teaches that the implant is "made of titanium or some other biocompatible material." (Tienboon, col. 6, lines 34-35). Gresser teaches that the implant is made of polymeric resorbable materials. (See Gresser, page 3, lines 3-24). Tropiano teaches that the implant is made of stainless steel, cobalt-chromium-molybdenum alloys, titanium, or the like." (Tropiano, col. 2, line 65 through col. 3, line 6). Applicant submits that Tienboon, Gresser, and Tropiano teach toward implants made of artificial materials and away from implants made of bone material obtained from a major long bone of a human.

Further, none of the openings in the implants of Tienboon, Gresser, and Tropiano are an "opening coincident with the medullary canal" as taught in Pafford and Boyle and recited in independent claims 1, 85, 163, 203, 223, and 263. Applicant submits that one of ordinary skill in the art would not be motivated to modify the location of the openings on the implants of Pafford and Boyle in view of the placement of dissimilar openings of dissimilar implants of Tienboon, Gresser, and Tropiano to result in an implant including openings as recited in Applicant's independent claims 1, 85, 163, 203, 223, and 263.

A recent precedential Board of Patent Appeals and Interferences decision interpreting KSR held that "when the prior art teaches away from the claimed solution ... obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success; it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that would result in the claimed composition." Ex parte Whalen II et al., BPAI Appeal No. 2007-4423 at p.16 (July 23, 2008). It is submitted that although Tienboon, Gresser, and Tropiano teach away from Pafford and Boyle, the Examiner has not shown why a person of ordinary skill would have had a reason to modify Pafford or Boyle in view of Tienboon, Gresser, or Tropiano

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to result in Applicant's claimed invention as recited in independent claims 1, 85, 163, 203, 223, and 263.

Applicant submits that the Examiner's rejections of independent claims 1, 85, 163, 203, 223, and 263 under 35 U.S.C. § 103(a) have been overcome.

Applicant submits that independent claims 1, 85, 163, 203, 223, and 263 are patentable and that dependent claims 2, 4, 5, 7-20, 22-30, 32-42, 86, 88, 89, 91-129, 148-152, 158-162, 164, 166, 168-182, 204, 206, 208-222, 224, 226, 228-242, 264, 266, and 268-300, dependent from one of independent claims 1, 85, 163, 203, 223 and 263, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, Applicant submits that the claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

MARTIN & FERRARO, LLP

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By: 

Amedeo F. Ferraro

Registration No. 37,129

1657 Lake O'Pines Street, NE
Hartsville, Ohio 44632
Telephone: (310) 286-9800
Facsimile: (310) 286-2795